FORMAL AEFI DATA :

Malaysia, VigiAccess (WHO/CDC), VAERS (USA & etc), YellowCard (UK), Eudravigilane (Europe)

NPRA (Ministry Of Health, Malaysia) AEFI REPORTS

OVERALL	As Of 8 April 2022 (start – 24 Feb 2021)
Total Dose Given	69,116,358
Total Number of AEFI Reports To NPRA	26,071
Rate of Reporting (Over Total Dose)	0.0377% = **377 reports per 1 million doses** *(Est rate over double vac person = 1010 per 1 million person ie 0.1%. Comparing to VAERS USA – 0.36%)*
Number And Rate Of **Serious AEFI** (Over Total Dose)	1,831 = 0.00265% = **27 per 1 million dose** *(= 7% of AEFI reports to NPRA are serious AEFIs.* *As 25.8 million Malaysian double vaccinated, rate of serious AEFI = **71 per 1 million double vac persons**)*
AEFI DEATH	**610 death** (460 – completed investigation – **none directly related to the vaccine**, 150 still under investigation. *(610 death = 2.3% of reported AEFI.* *= 8.8 death permillion dose.* ***= est 24 death per million fully vac persons = 0.0024% compared to vaers usa 0.0053%**)*
Number and Rate of **Non-Serious AEFI**	24,240 = 93%

https://m.facebook.com/story.php?story_fbid=355832186578791&id=100064560379224

NPRA (Ministry Of Health, Malaysia) AEFI REPORTS

Vaccination of 5 – 11 year olds	Up to 8th April 2022
Total dose given	1,436,625
Number and rate of AEFI reports	288 = 201 per 1 million doses
Number and Rate of Serious AEFI Over Total Dose	**18** = **12.5 per 1 million doses**. 17 warded- 5 fully recovered , 12 recovering. **1 brought in dead**, still under investigation
Non Serious AEFI	94% of reported AEFI *(6% of all reported AEFI = serious AEFI)*
Reporting Rate	0.2 per 1000 doses (Malaysia) Equivalent to the rate seen in some other countries: Canada 0.2 / 1000 doses Australia 0.6 / 1000 doses No safety issues detected

https://m.facebook.com/story.php?story_fbid=3558321865787 91&id=100064560379224

NPRA (Ministry Of Health, Malaysia) AEFI REPORTS

BOOSTER	Malaysia up t0 8th April 2022 (starts – 13 October)
Total Doses	15,889,555
Total AEFI Reported	1,552 = 98 per 1 million doses
Number and rate of serious AEFI	137 = 9% reported AEFI = 9 per 1 million booster doses given
AEFI Death	57 = 3.6% of AEFI Reported = 42% of serious AEFI 25 completed investigations – no relationship with the vaccine received. 32 still under investigation

https://m.facebook.com/story.php?story_fbid=3558321865787 91&id=100064560379224

The WHO Programme for International Drug Monitoring

A global collaboration to advance the practice of pharmacovigilance in countries across the world.

http://vigiaccess.org/

Safety in numbers

The WHO PIDM was created in 1968 to ensure that evidence about harm to patients was collected from as many sources as possible. This enables individual countries to be alerted to patterns of harm emerging across the world, but which might not be evident from their local data alone.

VigiAccess

World Health Organization

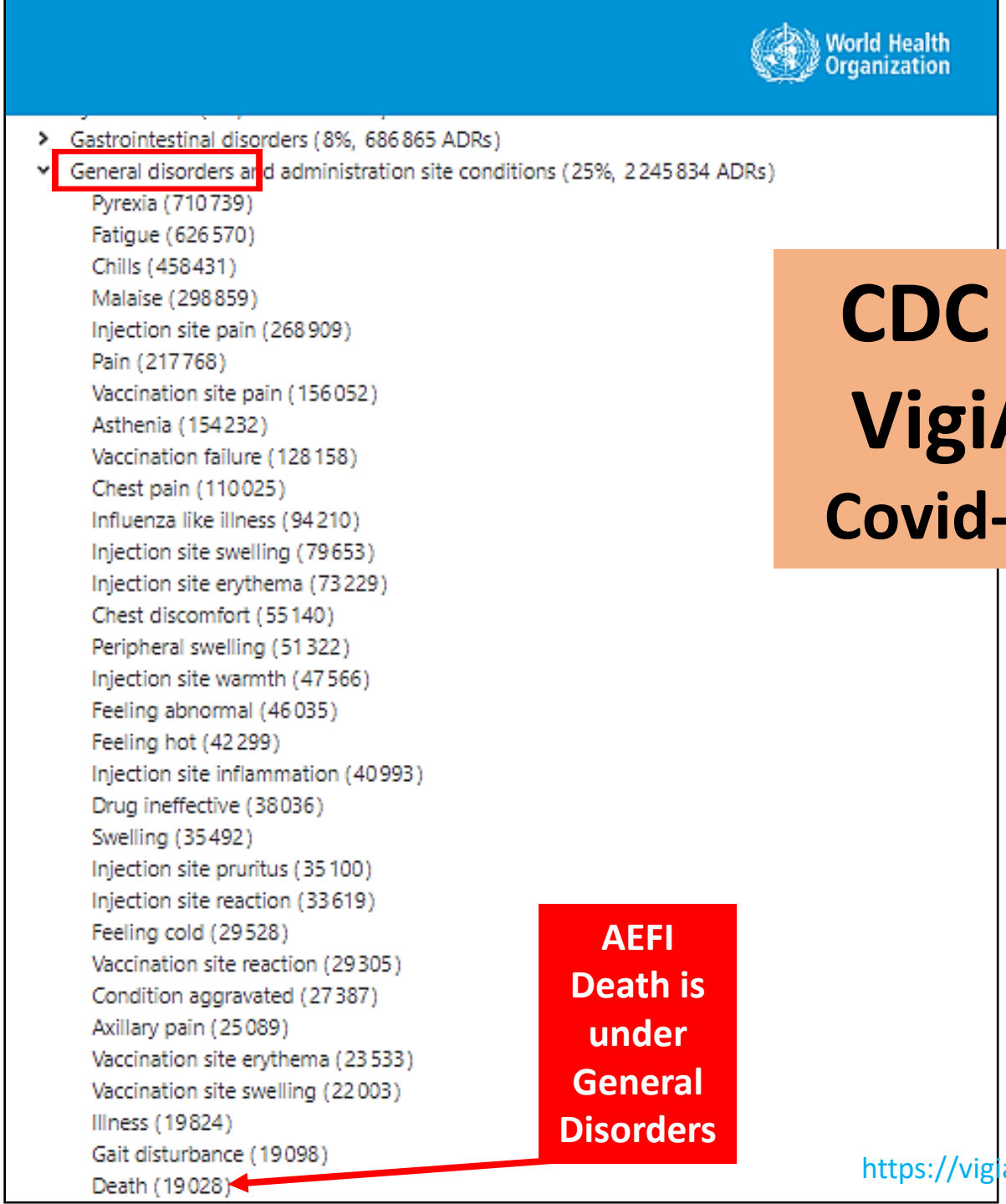
COVID-19 vaccine is an active ingredient

There are **3 777 652** reports with this active ingredient

https://vigiaccess.org/ (Date of website visit : 17th May 2022)

Reported potential side effects

- Blood and lymphatic system disorders (2%, 174 921 ADRs)
- Cardiac disorders (3%, 239 618 ADRs)
- Congenital, familial and genetic disorders (0%, 2 663 ADRs)
- Ear and labyrinth disorders (1%, 119 679 ADRs)
- Endocrine disorders (0%, 8 015 ADRs)
- Eye disorders (1%, 133 409 ADRs)
- Gastrointestinal disorders (8%, 686 865 ADRs)
- General disorders and administration site conditions (25%, 2 245 834 ADRs)
- Hepatobiliary disorders (0%, 8 800 ADRs)



CDC / WHO : VigiAccess – Covid-19 Vaccine

https://vigiaccess.org/ (As of 17th May 2022)

Reported potential side effects

27 Groups of side effects

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- Cardiac disorders (3%, 239 618 ADRs)
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- Eye disorders (1%, 133 409 ADRs)
- Gastrointestinal disorders (8%, 686 865 ADRs)
- General disorders and administration site conditions (25%, 2 245 834 ADRs)
- Hepatobiliary disorders (0%, 8 800 ADRs)
- Immune system disorders (1%, 65 356 ADRs)
- Infections and infestations (5%, 409 839 ADRs)
- Injury, poisoning and procedural complications (3%, 229 443 ADRs)
- Investigations (6%, 581 712 ADRs)
- Metabolism and nutrition disorders (1%, 77 732 ADRs)
- Musculoskeletal and connective tissue disorders (11%, 1 000 496 ADRs)
- Neoplasms benign, malignant and unspecified (incl cysts and polyps) (0%, 8 426 ADRs)
- Nervous system disorders (16%, 1 491 461 ADRs)
- Pregnancy, puerperium and perinatal conditions (0%, 11 024 ADRs)
- Product issues (0%, 5 827 ADRs)
- Psychiatric disorders (2%, 171 039 ADRs)
- Renal and urinary disorders (0%, 33 520 ADRs)
- Reproductive system and breast disorders (2%, 205 343 ADRs)
- Respiratory, thoracic and mediastinal disorders (4%, 397 719 ADRs)
- Skin and subcutaneous tissue disorders (5%, 474 323 ADRs)
- Social circumstances (0%, 28 979 ADRs)
- Surgical and medical procedures (1%, 78 439 ADRs)
- Vascular disorders (2%, 191 711 ADRs)

https://vigiaccess.org/ (As of 17th May 2022)

CDC / WHO : VigiAccess – Covid-19 Vaccine

Geographical distribution

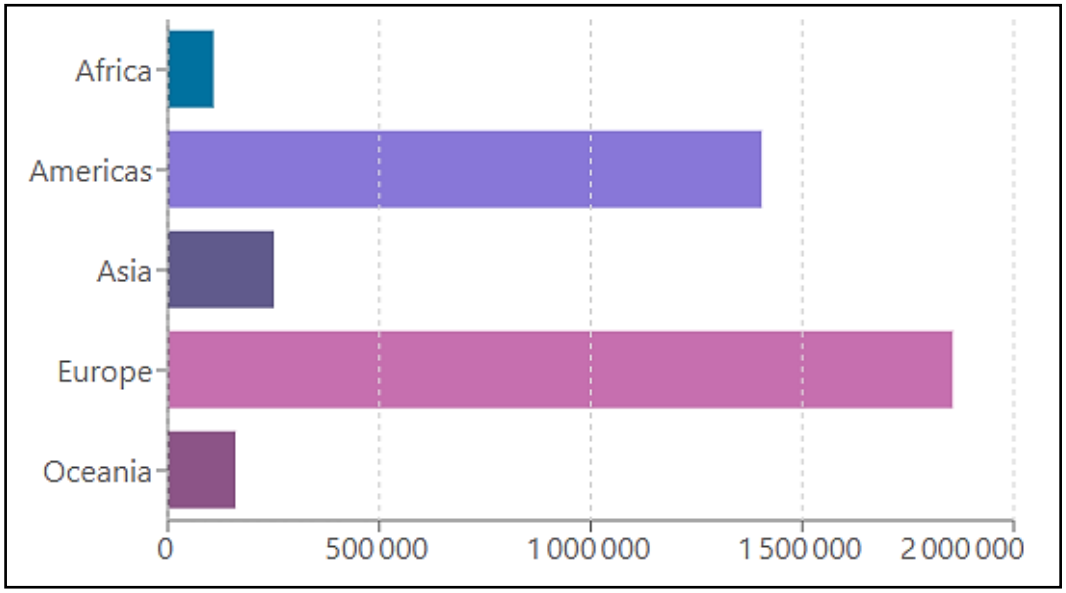
Chart | Table

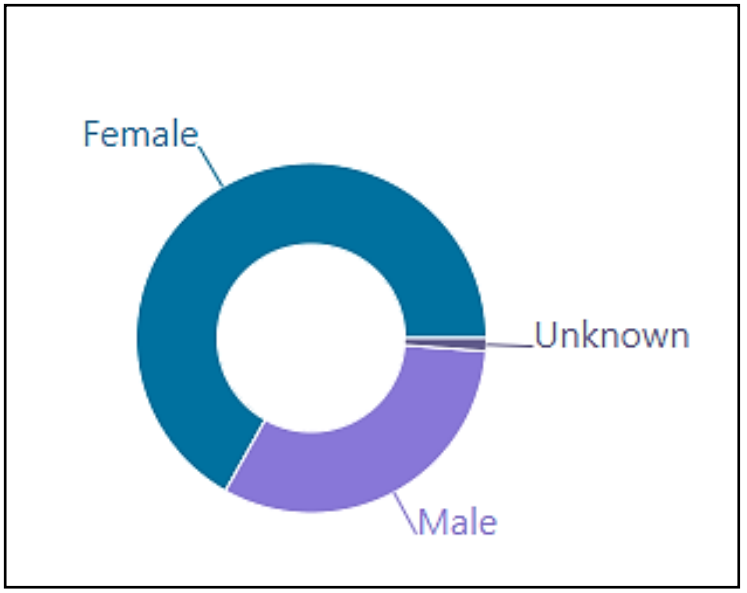
Continent	Count	Percentage
Africa	107 798	3
Americas	1 404 022	37
Asia	250 455	7
Europe	1 855 430	49
Oceania	159 947	4

Patient sex distribution

Chart | Table

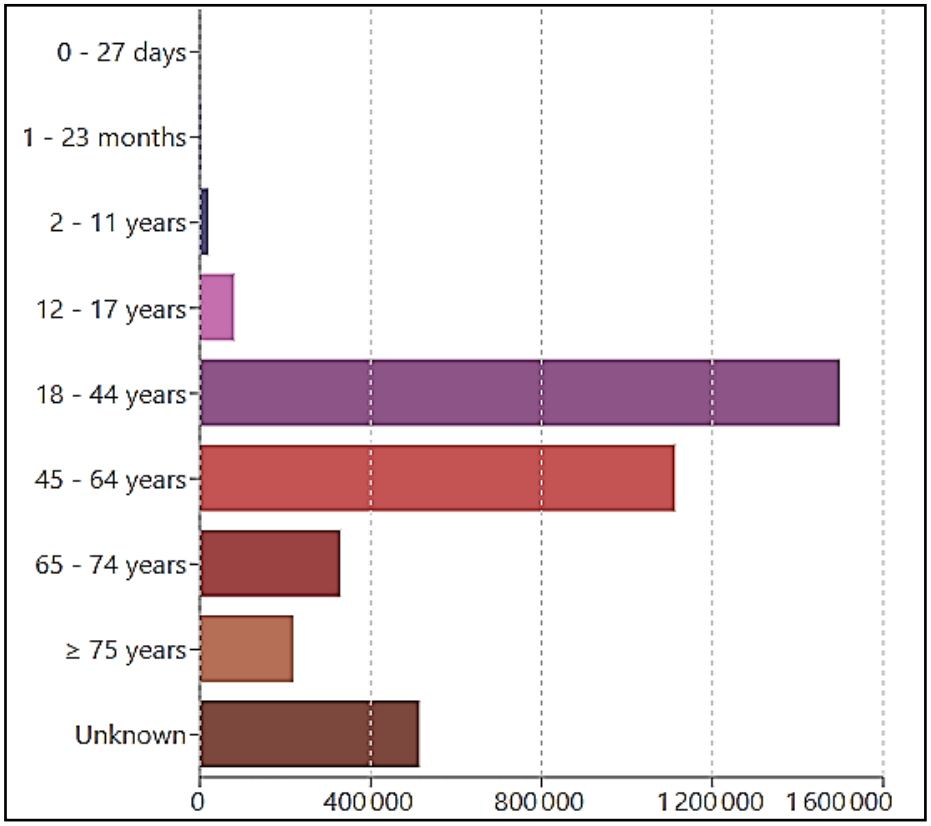
Sex	Count	Percentage
Female	2 526 051	67
Male	1 206 612	32
Unknown	44 989	1





https://vigiaccess.org/ (As of 17th May 2022

CDC / WHO : VigiAccess – Covid-19 Vaccine



Age group distribution

Chart | Table

Age group	Count	Percentage
0 - 27 days	577	0
28 days to 23 months	2236	0
2 - 11 years	20377	1
12 - 17 years	80357	2
18 - 44 years	1498910	40
45 - 64 years	1112730	29
65 - 74 years	329576	9
≥ 75 years	218569	6
Unknown	514320	14

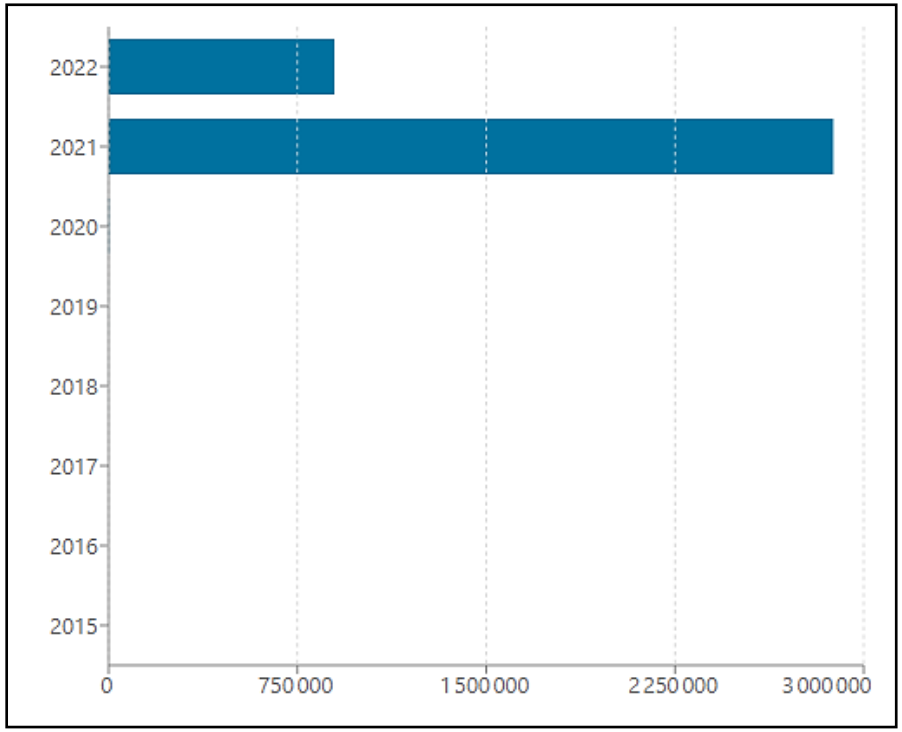
https://vigiaccess.org/ (As of 17th May 2022)

CDC / WHO : VigiAccess – Covid-19 Vaccine

ADR reports per year

Chart | Table

Year	Count	Percentage
2022	896 311	24
2021	2 878 845	76
2020	2 341	0
2019	109	0
2018	40	0
2017	3	0
2016	1	0
2015	2	0



https://vigiaccess.org/ (As of 17th May 2022)

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

VAERS Home

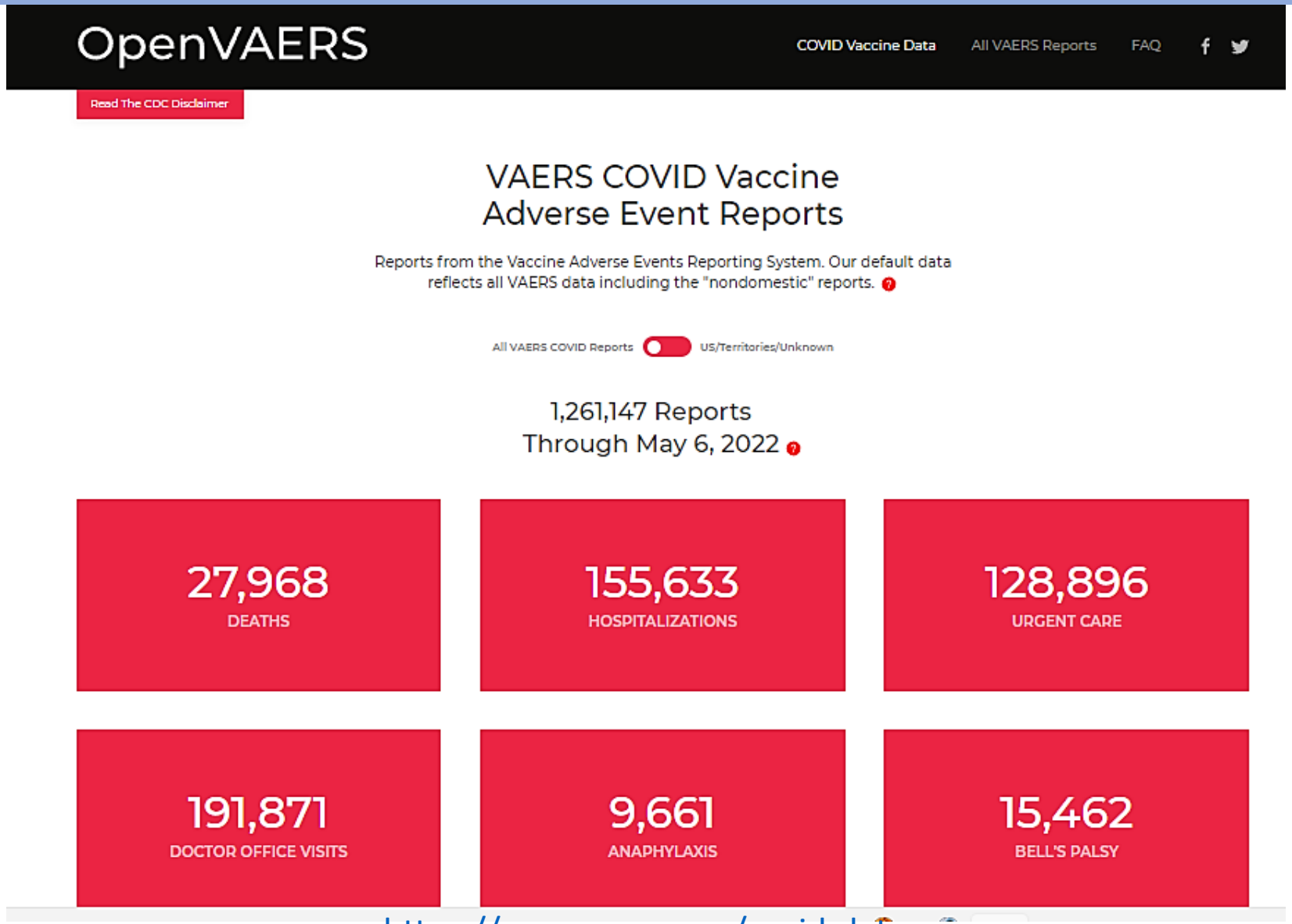
- VAERS Home
- About VAERS
- Report an Adverse Event +
- VAERS Data +
- Resources +
- Submit Follow-Up Information
- Frequently Asked Questions
- Contact Us
- Privacy

About VAERS

Background and Public Health Importance

Established in 1990, the Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.

VAERS (Vaccine Adverse Events Reporting System) – USA & Nondomestic Reports



https://openvaers.com/covid-data

Read The CDC Disclaimer

VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

All VAERS COVID Reports — US/Territories/Unknown

815,383 (US) Reports Through May 6, 2022

12,899 DEATHS	**61,955** HOSPITALIZATIONS	**99,918** URGENT CARE
161,859 DOCTOR OFFICE VISITS	**2,321** ANAPHYLAXIS	**3,184** BELL'S PALSY

VAERS (Vaccine Adverse Events Reporting System) – USA

815,383 (US) Reports
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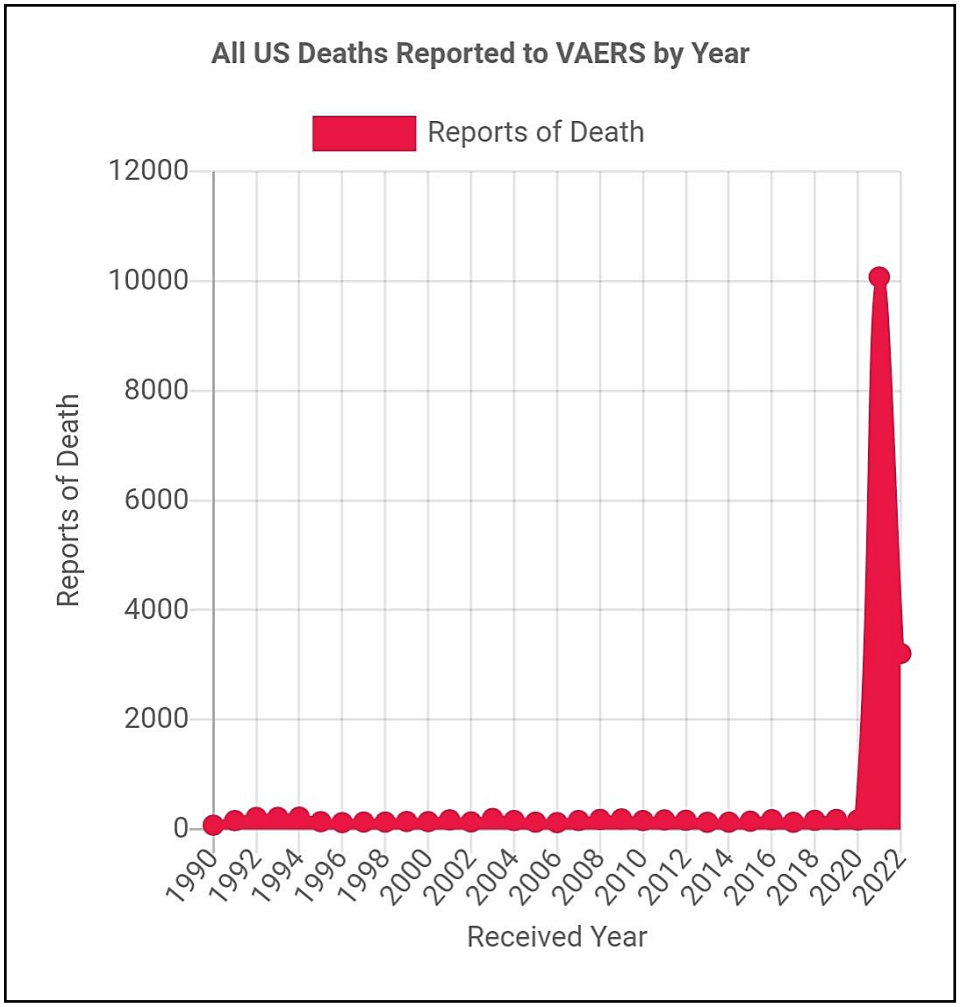
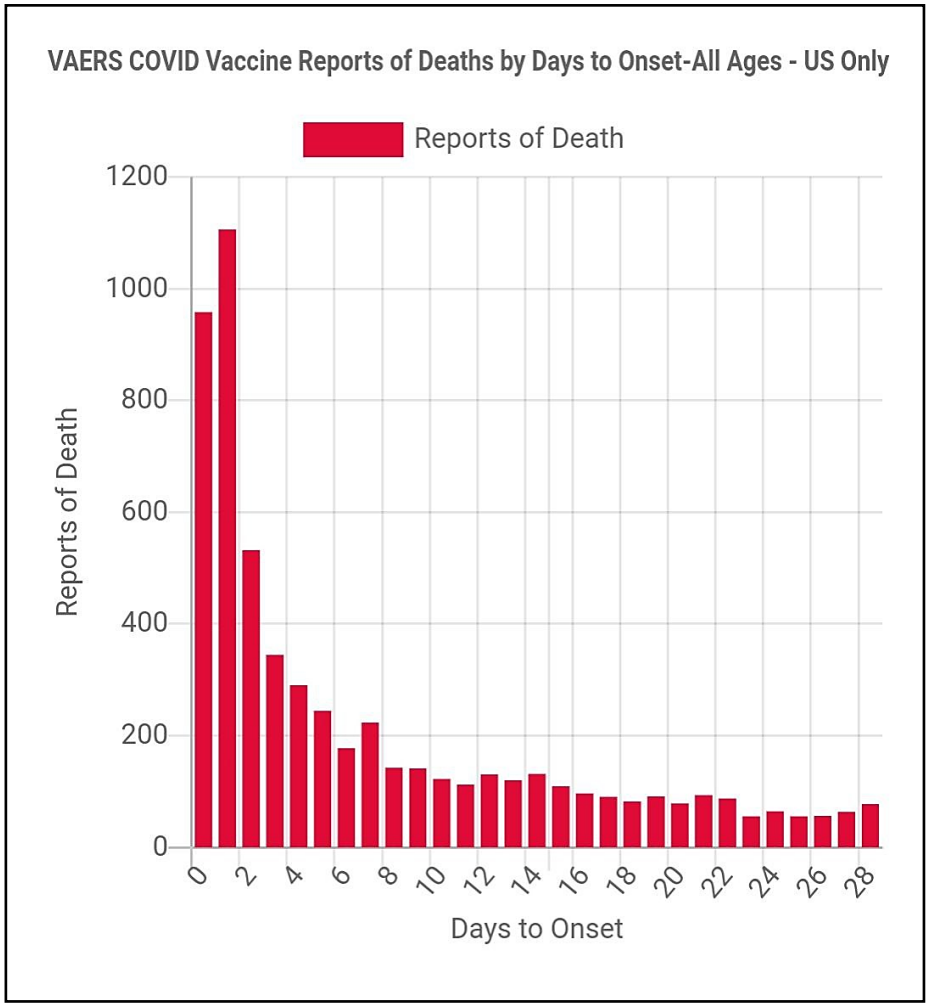
161,859 DOCTOR OFFICE VISITS	**2,321** ANAPHYLAXIS	**3,184** BELL'S PALSY

https://openvaers.com/covid-data

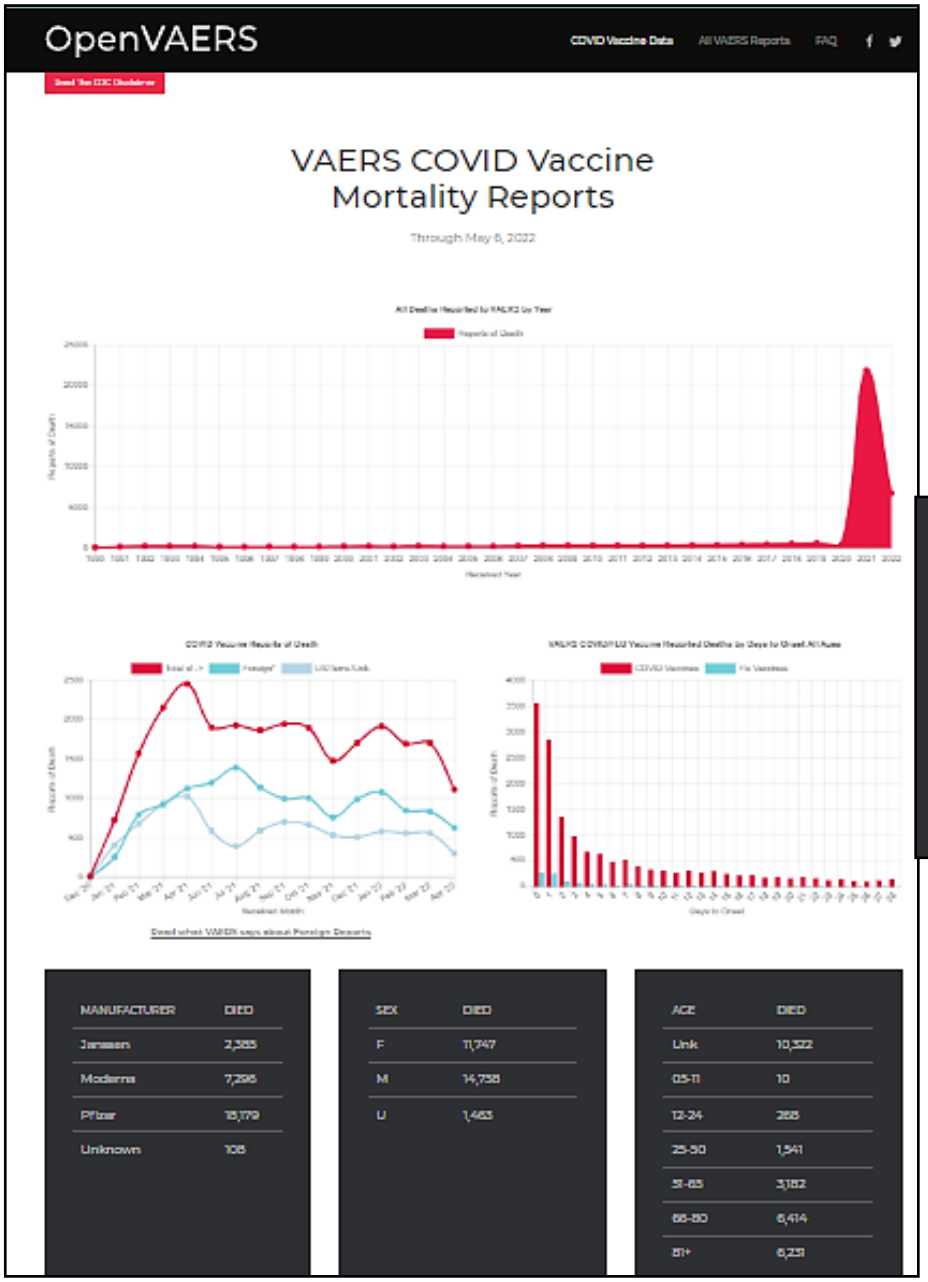
1,706 Miscarriages	5,811 Heart Attacks	5,348 Myocarditis/Pericarditis	13,997 Permanently Disabled
1,804 Thrombocytopenia/ Low Platelet	12,621 Life Threatening	30,821 Severe Allergic Reaction	7,639 Shingles

VAERS (Vaccine Adverse Events Reporting System)– USA





https://openvaers.com/covid-data



VAERS (Vaccine Adverse Events Reporting System)– Mortality (USA & Nondomestic)

MANUFACTURER	DIED
Janssen	2,385
Moderna	7,296
Pfizer	18,179
Unknown	108

SEX	DIED
F	11,747
M	14,758
U	1,463

AGE	DIED
Unk	10,322
05-11	10
12-24	268
25-50	1,541
51-65	3,182
66-80	6,414
81+	6,231

https://openvaers.com/covid-data/mortality

VAERS (Vaccine Adverse Events Reporting System) – Children Summaries

COVID Vaccine Reports in Children (Ages 5-17)

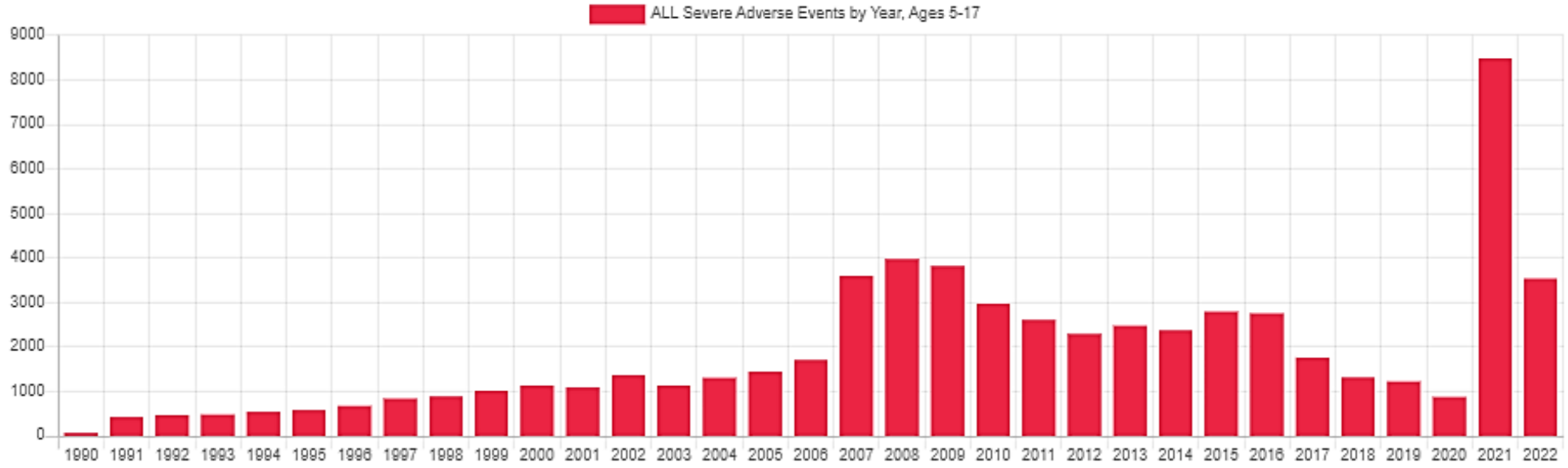
Through May 6, 2022

Deaths	Permanently Disabled	Myocarditis
108	436	1,298

47973	599	3778	4726	8620
Total Reports	Life Threatening	Hospitalized	ER Visit	Not Recovered

https://openvaers.com/covid-data/child-summaries

VAERS (Vaccine Adverse Events Reporting System) – Children Summaries



https://openvaers.com/covid-data/child-summaries

VAERS
(Vaccine Adverse Events Reporting System)
– Children Summaries

79
Encephalitis/ Encephalopathy
Encephalitis, Encephalopathy, AntiNMDA Antibodies, AntiMyelin Antibodies

207
Bell's Palsy
Bell's Palsy, Facial Paralysis, Facial Palsy, Facial Nerve Disorder

1,490
Severe Allergy
Epi Pen, Epinephrine, Rashes/Hives, Swelling, Anaphylaxis

3,840
Migraine/Headache
Migraine, Headache

25
Aneurysm/Cerebral Haemorrhage
Brain Haemorrhage, Aneurysm, Cerebral Infarction, CVST

176
Thrombocytopenia/ Low Platelets
Thrombocytopenia, Platelet Count Decreased

65
Guillain Barre/ Paralysis
Guillain Barre, Transverse Myelitis, Acute Disseminated Encephalomyelitis

104
Diabetes
Diabetes, High Blood Sugar, Diabetic Ketoacidosis

108
Appendicitis
Appendicitis, Appendicectomy

https://openvaers.com/covid-data/child-summaries

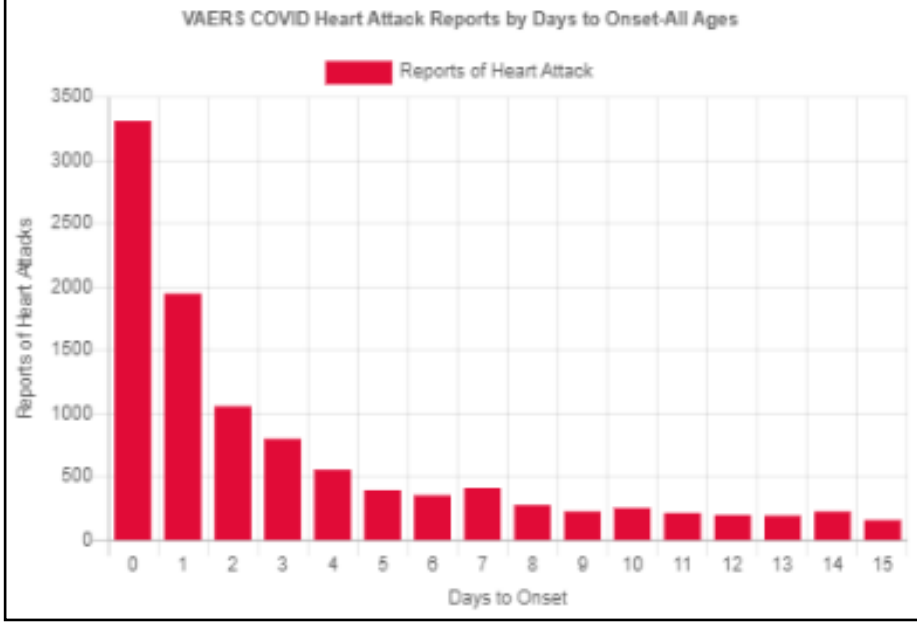
VAERS COVID Vaccine
Cardiac Reports

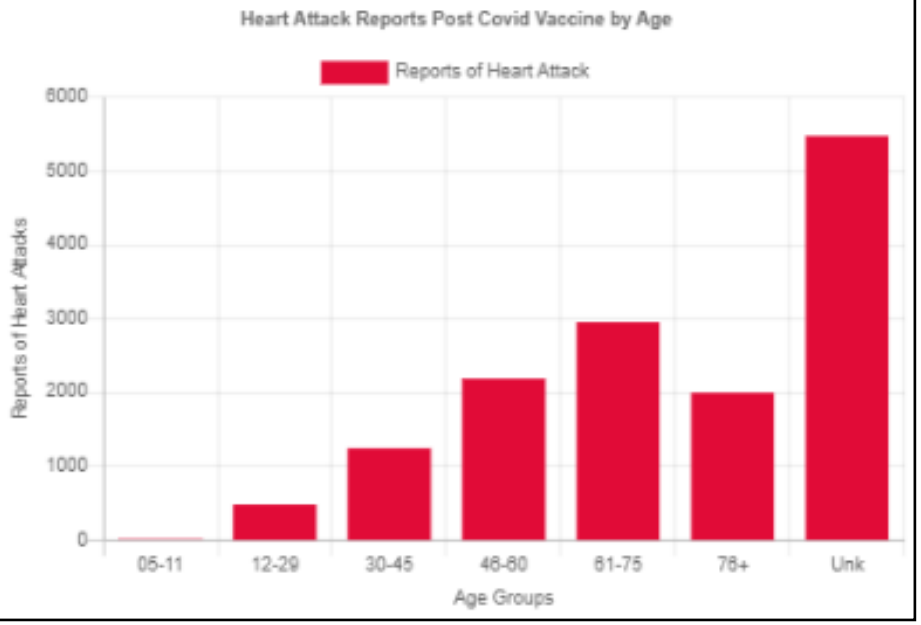
VAERS COVID Vaccine
Cardiac Reports

See the NEW Myocarditis Page →

Through May 6, 2022

Heart Attacks

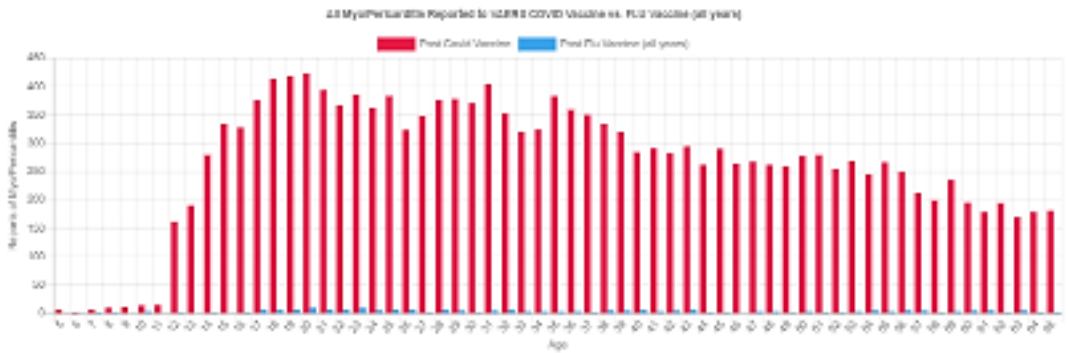


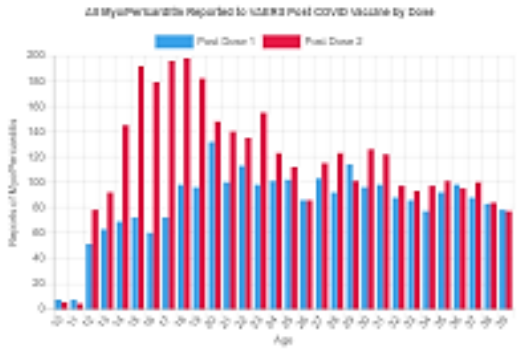


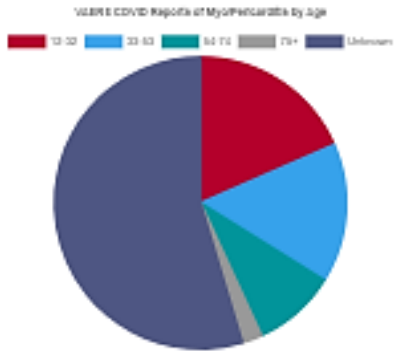
https://openvaers.com/covid -data/cardiac

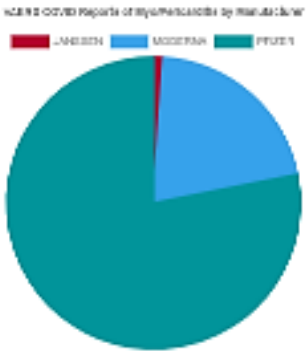
VAERS COVID Vaccine
Myo/Pericarditis Reports

Through May 6, 2022



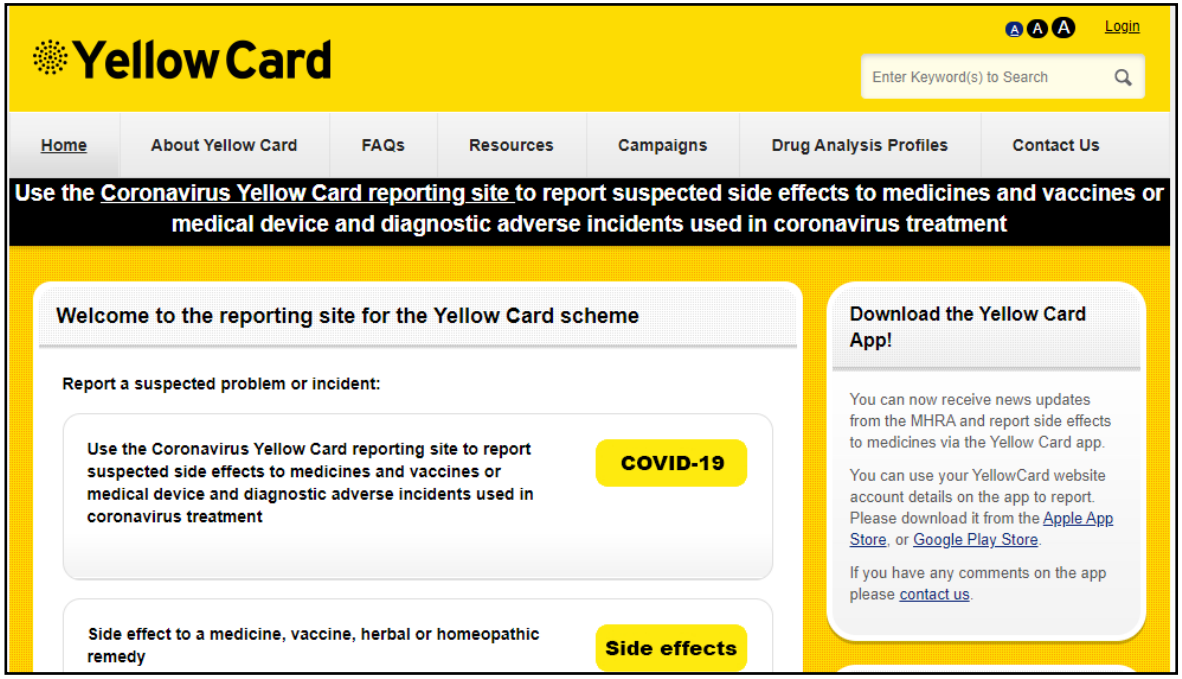


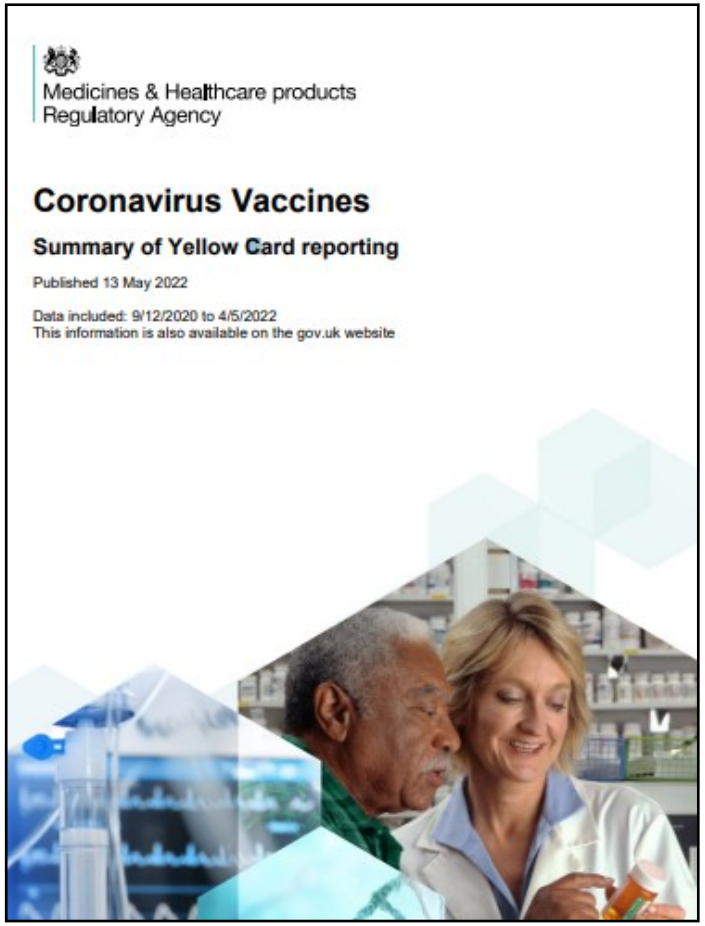




https://openvaers.com/covid-data/myo-pericarditis

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS





https://yellowcard.mhra.gov.uk/
https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075190/Coronavirus_vaccine_-_summary_of_Yellow_Card_reporting_4.05.2022.pdf

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS

Table 4: Number of suspected ADR reports received in the UK up to and including 4 May 2022.

	Number of reports			
Country	**COVID-19 Pfizer/ BioNTech Vaccine**	**COVID-19 Vaccine AstraZeneca**	**COVID-19 Vaccine Moderna**	**Brand unspecified**
England	132,890	201,891	30,558	1,003
Wales	8,211	10,843	2,271	93
Northern Ireland	3,007	2,989	147	20
Scotland	12,804	17,477	3,298	172

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075190/Coronavirus_vaccine_-_summary_of_Yellow_Card_reporting_4.05.2022.pdf (page 12 of 41)

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS

Table 9*: Number of UK ADR reports associated with suspected myocarditis, pericarditis and other related terms received for the COVID-19 Vaccine AstraZeneca, COVID-19 Pfizer/BioNTech Vaccine and COVID-19 Vaccine Moderna by patient age up to and including 4 May 2022.

Age range (years)	Number of reports		
	COVID-19 Pfizer/BioNTech Vaccine	COVID-19 Vaccine Moderna	COVID-19 Vaccine AstraZeneca
Under 18	77	0	0
18-29	382	119	31
30-39	308	95	48
40-49	140	52	115
50-59	97	22	103
60+	151	17	104
Unknown	150	34	46
Total	**1305**	**339**	**447**

* Due to the dynamic nature of the Yellow Card data these figures may change both as new cases are received, and as duplicate cases are identified and managed.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075190/Coronavirus_vaccine_-_summary_of_Yellow_Card_reporting_4.05.2022.pdf (page 31 of 41)

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine or vaccine may have caused the adverse reaction. The existence of an adverse reaction report in the print does not necessarily mean that the vaccine has caused the suspected reaction.

- It may be difficult to tell the difference between something that has occurred naturally and a suspected adverse reaction. Sometimes these events can be part of the condition being treated rather than being caused by the vaccine.

- Many factors have to be considered when assessing whether the vaccine has caused a reported adverse reaction. When monitoring the safety of vaccines and medicines, MHRA staff carry out careful analysis of these factors.

For a medicine or vaccine to be considered safe, the expected benefits will be greater than the risk of having harmful reactions. It is important to note that most people take medicines and vaccines without having any serious side effects.

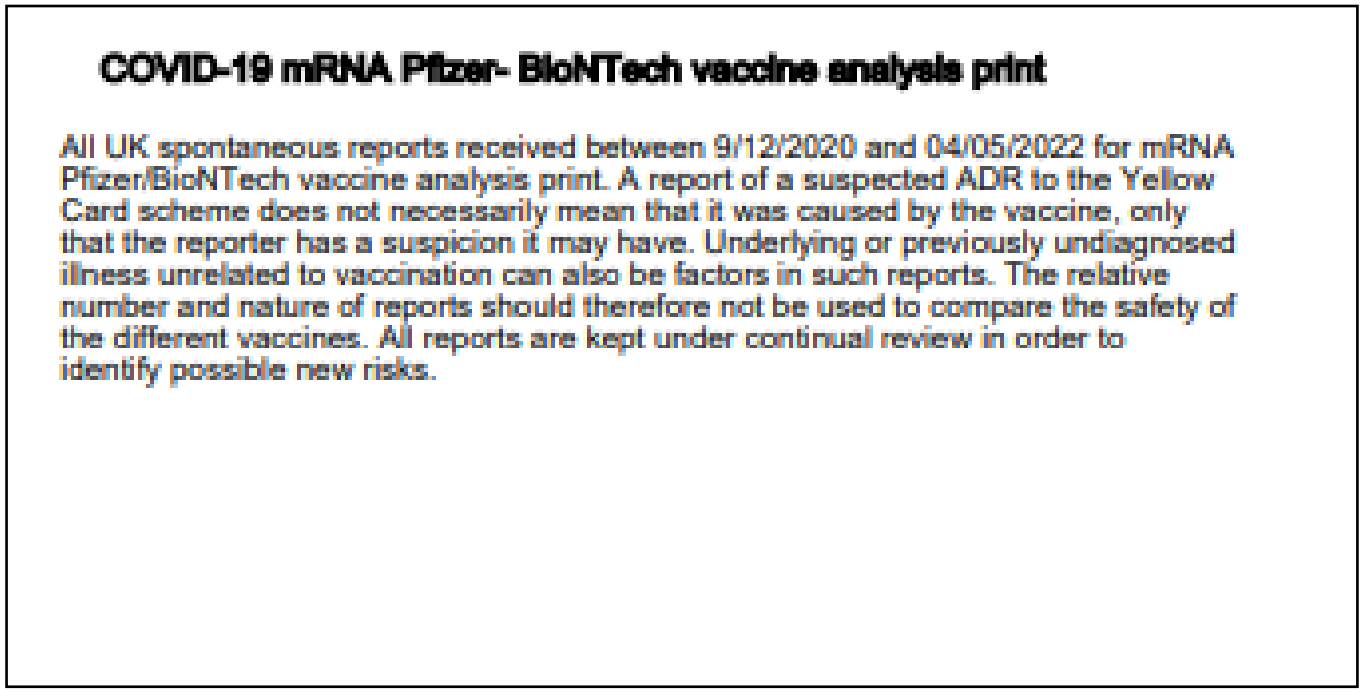
Vaccine Analysis Print – COVID-19 Pfizer/BioNTech Vaccine

Vaccine Analysis Print - COVID-19 Vaccine AstraZeneca

Vaccine Analysis Print – COVID-19 Vaccine Moderna

Vaccine Analysis Print - Brand unspecified

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS



COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

All UK spontaneous reports received between 9/12/2020 and 04/05/2022 for mRNA Pfizer/BioNTech vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075148/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_4.05.2022.pdf (1 of 117 pages)

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS - PFIZER

1. Blood disorders : 17097, 4 Fatal
2. Cardiac disorders : 13266, 155 Fatal
3. Congenital disorders : 107, 1
4. Ear disorders : 6689 , 0 Fatal
5. Endocrine disorders : 382, 0 Fatal
6. Eye disorders : 8084 0 Fatal
7. Gastrointestinal disorders : 42582, 19 Fatal
8. General disorders : 122192, 2 Fatal
9. Hepatic disorders : 269, 1 Fatal
10. Immune system disorders : 2520, 2 Fatal

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075148/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_4.05.2022.pdf

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS - PFIZER

11. Infections : 12462, 116 Fatal
12. Injuries : 8045, 1 Fatal
13. Investigations : 6463, 3 Fatal
14. Metabolic disorders : 2787, 2 Fatal
15. Muscle & tissue disorders : 56150, 1 Fatal
16. Neoplasms : 388 11, Fatal
17. Nervous system disorders : 81422, 91 Fatal
18. Pregnancy conditions : 733, 14 Fatal
19. null : 131, 0 Fatal
20. Psychiatric disorders : 10270, 3 Fatal

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075148/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_4.05.2022.pdf

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS - PFIZER

21. Renal & urinary disorders : 1424, 8 Fatal
22. Reproductive & breast disorders : 31372, 1 Fatal
23. Respiratory disorders : 21919, 63 Fatal
24. Skin disorders : 34354, 2 Fatal
25. Social circumstances : 305, 0 Fatal
26. Surgical & medical procedures : 1214, 1 Fatal
27. Vascular disorders : 7607, 21 Fatal

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075148/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_4.05.2022.pdf

Red ear syndrome	2	0
External ear infections and inflammations		
Chondrodermatitis nodularis chronica helicis	1	0
External ear inflammation	2	0
Hearing disorders NEC		
Auditory disorder	6	0
Diplacusis	2	0
Dysacusis	1	0
Hearing losses		
Conductive deafness	1	0
Deafness	306	0
Deafness bilateral	12	0
Deafness neurosensory	27	0
Deafness transitory	10	0
Deafness unilateral	40	0
Hypoacusis	231	0
Mixed deafness	1	0
Sudden hearing loss	52	0
Hyperacusia		
Hyperacusis	79	0
Misophonia	3	0
Inner ear disorders NEC		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	16	0
Vestibular disorder	15	0
Inner ear infections and inflammations		
Autoimmune inner ear disease	1	0
Inner ear inflammation	11	0
Inner ear signs and symptoms		
Motion sickness	70	0
Phobic postural vertigo	1	0

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075148/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_4.05.2022.pdf

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	4	0
Blindness	166	0
Blindness cortical	1	0
Blindness transient	21	0
Blindness unilateral	20	0
Central vision loss	6	0
Sudden visual loss	5	0
Visual acuity reduced	30	0
Visual acuity reduced transiently	1	0
Visual impairment	472	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	**8084**	**0**

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vascular disorders SOC TOTAL	7607	21
TOTAL REACTIONS FOR DRUG	490234	763
TOTAL REPORTS	170337	
TOTAL FATAL OUTCOME REPORTS		763

UNITED KINGDOM – COVID VACCINE ADVERSE REPORTS – PFIZER, ASTRAZENECA, MODERNA & UNSPECIFIED VACCINE

TOTAL REACTIONS FOR DRUG	490234	763
TOTAL REPORTS	170337	
TOTAL FATAL OUTCOME REPORTS		763

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075148/COVID-19_Pfizer BioNTech_Vaccine_Analysis_Print_DLP_4.05.2022.pdf (117 pages) UK - **PFIZER**

TOTAL REACTIONS FOR DRUG	868095	1272
TOTAL REPORTS	245089	
TOTAL FATAL OUTCOME REPORTS		1272

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075149/COVID-19_AstraZeneca_Vaccine_Analysis_Print_DLP_4.05.2022.pdf (131 pages) UK - **ASTRA ZENECA**

TOTAL REACTIONS FOR DRUG	126834	53
TOTAL REPORTS	38197	
TOTAL FATAL OUTCOME REPORTS		53

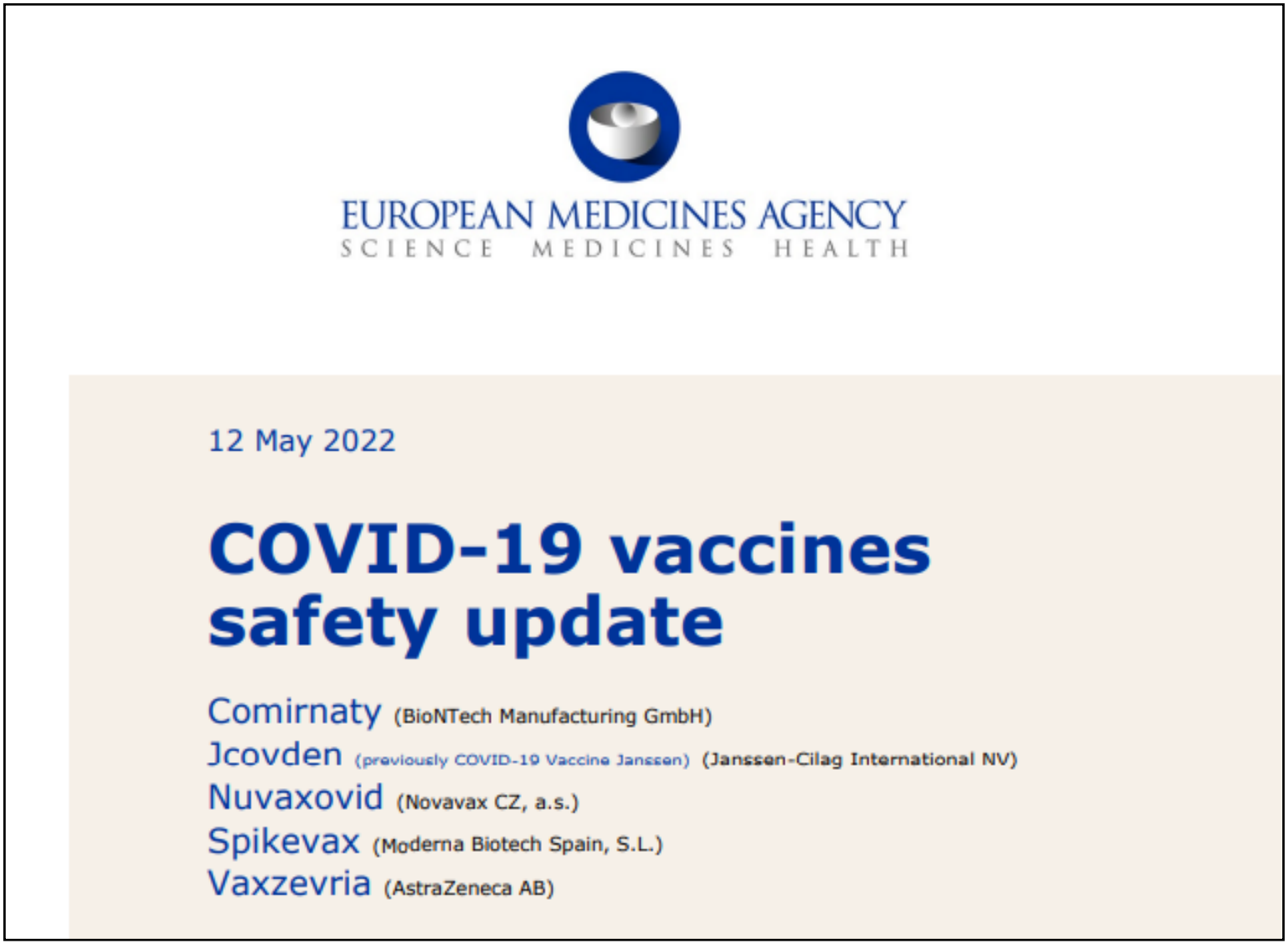
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075147/COVID-19_Moderna_Vaccine_Analysis_Print_DLP_4.05.2022.pdf (66 pages) UK - **MODERNA**

TOTAL REACTIONS FOR DRUG	5108	44
TOTAL REPORTS	1672	
TOTAL FATAL OUTCOME REPORTS		44

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1075146/COVID-19_Brand_Unspecified_Vaccine_Analysis_Print_DLP_4.05.2022.pdf (39 pages) UK – **BRAND UNSPECIFIED**

TOTAL REACTION	**1,049,060**
TOTAL REPORTS	**455,295**
TOTAL FATAL OUTCOME REPORTS	**2132**

Europe – Covid Vaccine Adverse Reports



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2022

COVID-19 vaccines safety update

Comirnaty (BioNTech Manufacturing GmbH)
Jcovden (previously COVID-19 Vaccine Janssen) (Janssen-Cilag International NV)
Nuvaxovid (Novavax CZ, a.s.)
Spikevax (Moderna Biotech Spain, S.L.)
Vaxzevria (AstraZeneca AB)

https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccines-safety-update-12-may-2022_en.pdf (7 pages)

Europe – Covid Vaccine Adverse Reports

As of 28 April 2022, EudraVigilance contained the following:

- Comirnaty: a total of 743,735 cases of suspected side effects spontaneously reported from EU/EEA countries; 7,765 of these reported a fatal outcome[4,5] (by 24 April 2022, about 627 million doses of Comirnaty had been given to people in the EU/EEA[6])
- Jcovden: a total of 48,410 cases of suspected side effects spontaneously reported from EU/EEA countries; 311 of these reported a fatal outcome[4,5,] (by 24 April 2022, about 19.4 million doses of COVID-19 Vaccine Janssen had been administered to people in the EU/EEA[6])
- Nuvaxovid: a total of 294 cases of suspected side effects spontaneously reported from EU/EEA countries; none of these reported a fatal outcome[4,5] (by 24 April 2022, about 178,000 doses of Nuvaxovid had been administered to people in the EU/EEA[6])
- Spikevax: a total of 206,920 cases of suspected side effects spontaneously reported from EU/EEA countries; 1,025 of these reported

https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccines-safety-update-12-may-2022_en.pdf (7 pages)

Europe – Covid Vaccine Adverse Reports

a fatal outcome[7,8] (by 24 April 2022, about 155 million doses of Spikevax had been given to people in the EU/EEA[9])

- Vaxzevria: a total of 276,697 cases of suspected side effects spontaneously reported from EU/EEA countries; 1,529 of these rep a fatal outcome[7,8] (by 24 April 2022, about 69 million doses of Vaxzevria had been given to people in the EU/EEA[9]).

These reports describe suspected side effects in individuals, i.e. medical events observed following the use of a vaccine. The fac that someone has had a medical issue or died after vaccination not necessarily mean that this was caused by the vaccine. This have been caused, for example, by health problems not related the vaccination.

https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccines-safety-update-12-may-2022_en.pdf (7 pages)

Total Dose Given (All Vaccines)	627 M + 19.4M + 178,000 + 155M + 69M =
Suspected Side Effects	743,735 + 48,410 + 294 + 206,920 + 276,697 = **1,276,056**
Fatal Outcome	7,765 + 311 + 0 + 1025 + 1529 = **10,630**

Europe – Covid Vaccine Adverse Reports

https://eudravigilance.ema.europa.eu/human/index.asp

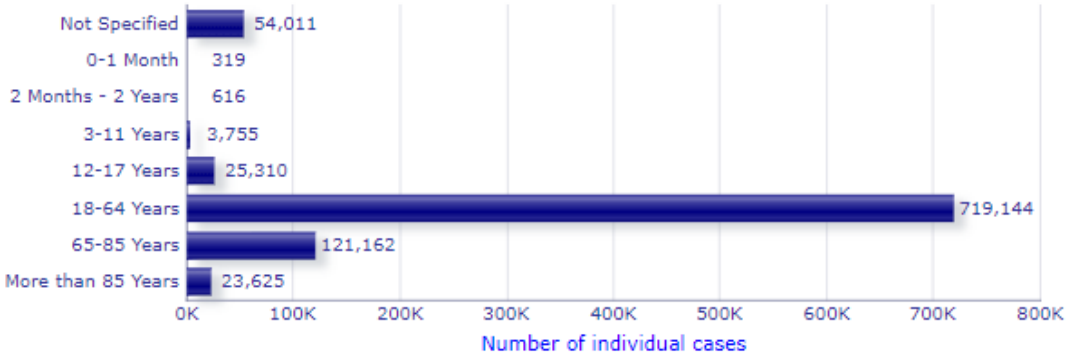
Europe – Covid Vaccine Adverse Reports

Number of Individual Cases | Number of Individual Cases received over time | Number of Individual Cases by EEA countries | Number of Individual Cases By Reaction Groups | Number of Individual Cases for a sele

The number of individual cases identified in EudraVigilance for **TOZINAMERAN** is **947,942** (up to 14/05/2022)

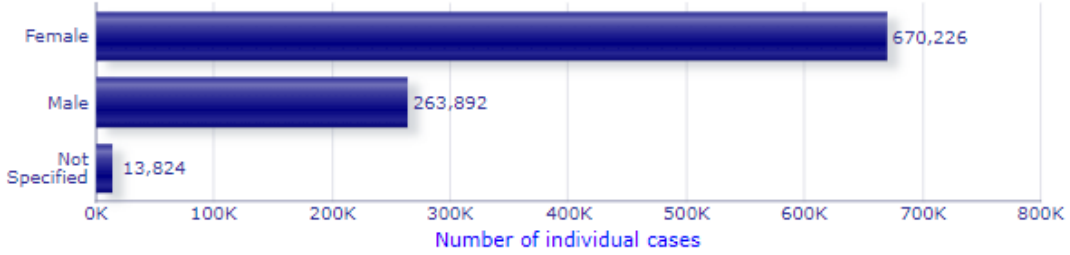
Number of individual cases by Age Group

Age Group	Cases	%
Not Specified	54,011	5.7%
0-1 Month	319	0.0%
2 Months - 2 Years	616	0.1%
3-11 Years	3,755	0.4%
12-17 Years	25,310	2.7%
18-64 Years	719,144	75.9%
65-85 Years	121,162	12.8%
More than 85 Years	23,625	2.5%
Total	**947,942**	**100.0%**



Number of individual cases by Sex

Sex	Cases	%
Female	670,226	70.7%
Male	263,892	27.8%
Not Specified	13,824	1.5%
Total	**947,942**	**100.0%**



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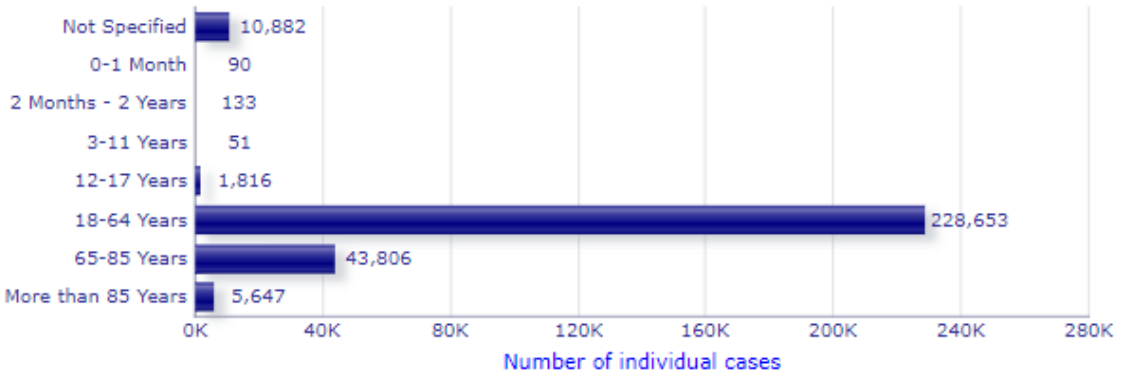
%22Line%20Listing%20Objects%22.%22Substance%20High%20Level%20Code%22&P3=1+42325700

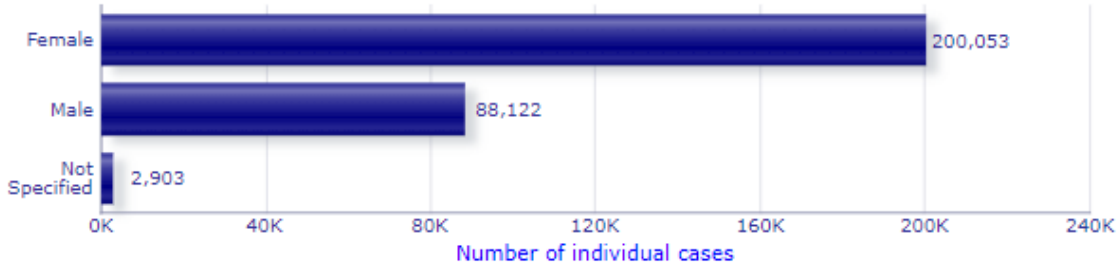
Europe – Covid Vaccine Adverse Reports

ses identified in EudraVigilance for **COVID-19 MRNA VACCINE MODERNA (CX-024414)** is **291,078** (up to 14/05/2022)

	%
,882	3.7%
90	0.0%
133	0.0%
51	0.0%
,816	0.6%
,653	78.6%
,806	15.0%
,647	1.9%
078	**100.0%**



	%
,053	68.7%
,122	30.3%
,903	1.0%
078	**100.0%**



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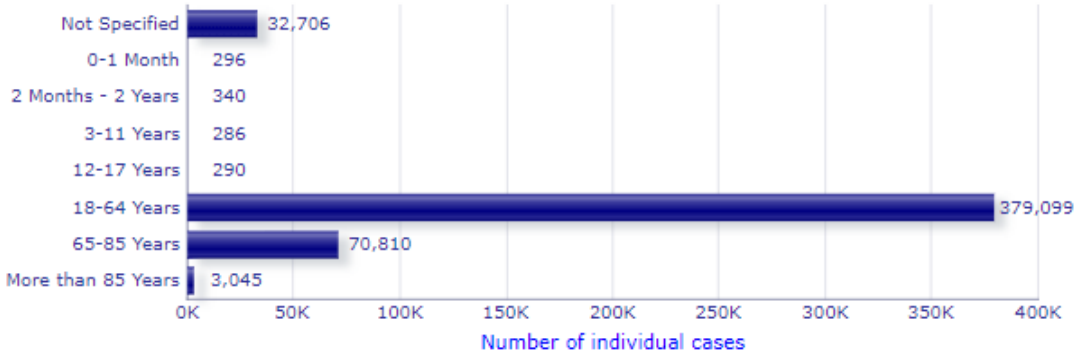
avigate&P0=1&P1=eq&P2=%22Line%20Listing%20Objects%22.%22Substance%20High%20Level%20
0983312

Europe – Covid Vaccine Adverse Reports

er of individual cases identified in EudraVigilance for **COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)** is **486,872** (up

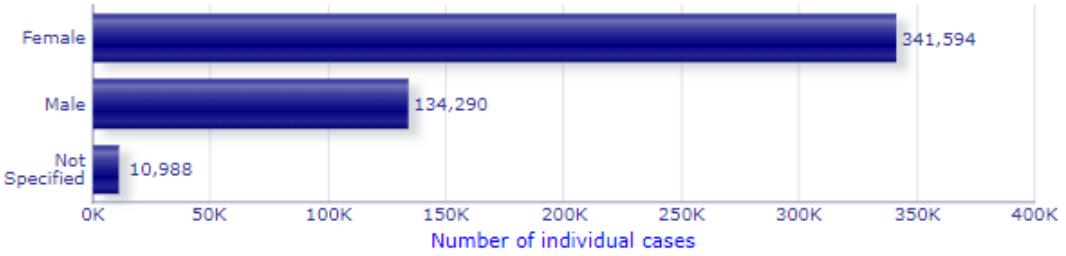
vidual cases by Age Group

roup	Cases	%
	32,706	6.7%
	296	0.1%
rs	340	0.1%
	286	0.1%
	290	0.1%
	379,099	77.9%
	70,810	14.5%
ars	3,045	0.6%
	486,872	**100.0%**



vidual cases by Sex

x	Cases	%
	341,594	70.2%
	134,290	27.6%
	10,988	2.3%
	486,872	**100.0%**



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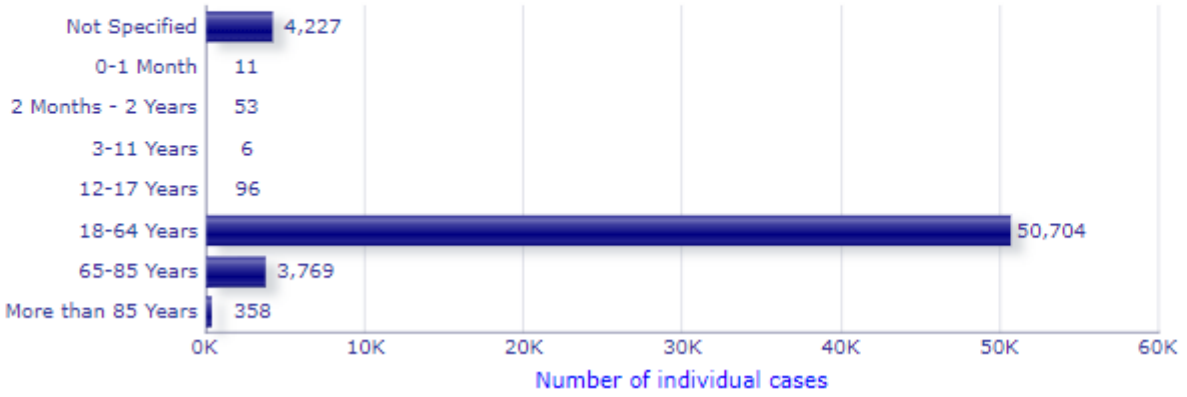
40995439

Europe – Covid Vaccine Adverse Reports

of individual cases identified in EudraVigilance for **COVID-19 VACCINE JANSSEN (AD26.COV2.S)** is **59,224** (up to

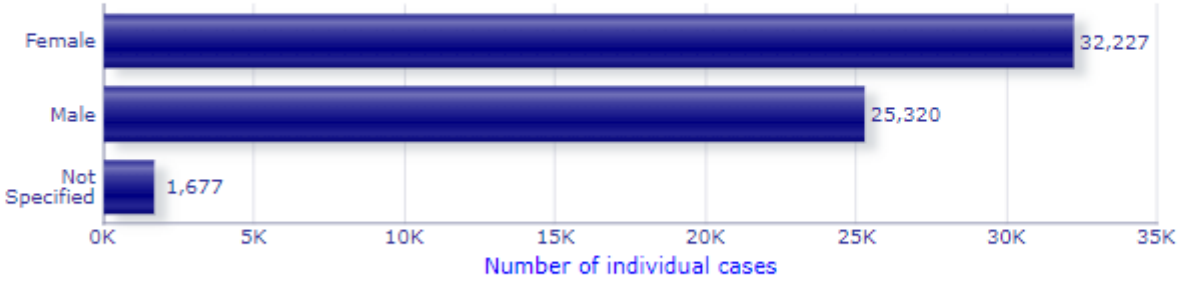
al cases by Age Group

	Cases	%
	4,227	7.1%
	11	0.0%
	53	0.1%
	6	0.0%
	96	0.2%
	50,704	85.6%
	3,769	6.4%
	358	0.6%
	59,224	**100.0%**



al cases by Sex

	Cases	%
	32,227	54.4%
	25,320	42.8%
	1,677	2.8%
	59,224	**100.0%**



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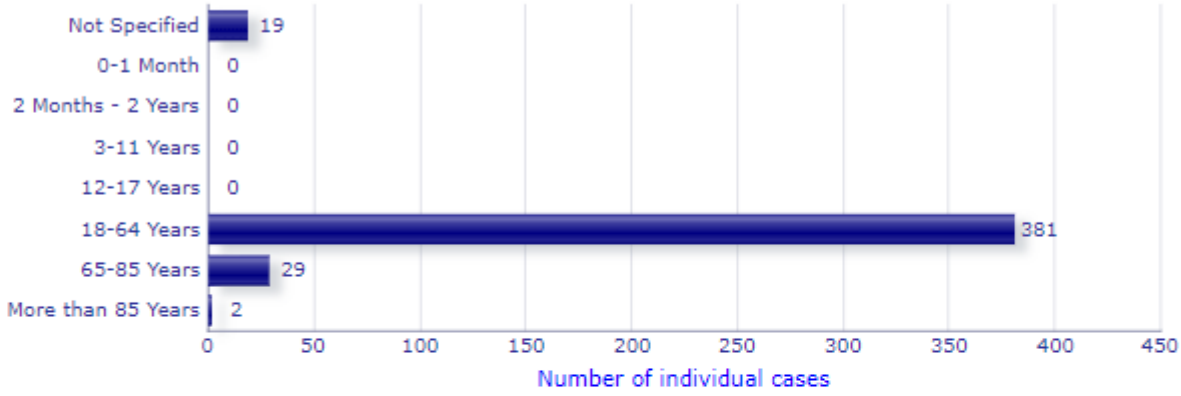
&P2=%22Line%20Listing%20Objects%22.%22Substance%20High%20Level%20Code%22&P3=1+42287887

Europe – Covid Vaccine Adverse Reports

The number of individual cases identified in EudraVigilance for **NVX-COV2373** is **431** (up to 14/05/2022)

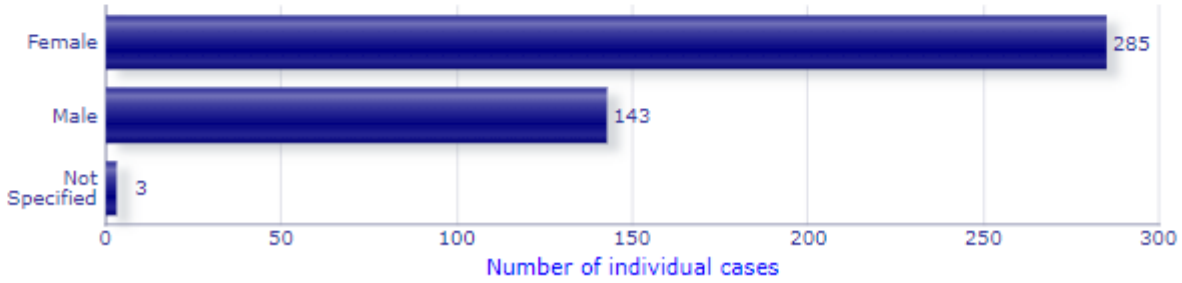
of individual cases by Age Group

Age Group	Cases	%
ified	19	4.4%
h	0	
- 2 Years	0	
rs	0	
ars	0	
ars	381	88.4%
ars	29	6.7%
n 85 Years	2	0.5%
	431	**100.0%**



of individual cases by Sex

Sex	Cases	%
	285	66.1%
	143	33.2%
ified	3	0.7%
	431	**100.0%**



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%20Listing%20Objects%22.%22Substance%20High%20Level%20Code%22&P3=1+42287687